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ART UNIT	**PAPER NUMBER**
1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,958	BURKE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *41-50,53-56 and 59* is/are allowed.

6)☒ Claim(s) *1-40,51,52,57,58 and 60-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/01/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDS of 08/15/2005; and IDS of 02/22/2005.

DETAILED ACTION

Information Disclosure Statement

1. Applicant's Information Disclosure Statement of February 22, 2005 ("IDS") contains a 38 page list of prior art documents, easily many hundreds, if not a few thousand pages of documents. Many of the references are merely background to the biosensor art. Some, such as US 5,745,308; US 4,329,642; and US 2002/013856 A1, are clearly irrelevant to the claimed invention. It is not clear to the Examiner whether by this voluminous IDS Applicant is admitting that the claimed invention must be unpatentable because there are so many materially relevant documents in his view.

Claim Rejections - 35 USC § 103

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design").

Addressing claim 1, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70), a reagent (90) disposed in the capillary fill chamber between the opening and the terminus (Figure 3), the reagent defining a measurement zone (Figures 2 and 3), and at least two dose sufficiency electrodes (60, 62) defining a gap therebetween (Figure 2)

and in operative communication with the capillary fill chamber (Figure 2), the electrodes located between the measurement zone and the terminus (Figure 2); applying the biological fluid to the opening (344- Figure 17), whereby the fluid flows from the opening toward the terminus (col. 14:43-51 and col. 14:63-65); applying a test signal to a first one of the electrodes (col. 14:66 – col. 15:03); determining the presence or absence of a response above a predetermined threshold at the second one of the electrodes, the response indicating that the fluid has occupied substantially all of the measurement zone (col. 15:03-11).

Neel does not mention whether the flow includes a flow front selected from one of a concave, a convex and a substantially flat flow front and thus whether the response indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to have the fill detection region adapted (if not already so adapted) so that the response of the second fill electrode indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat because Neel desires for the sample to reach the fill electrodes not only until after the sample has traversed the reagent layer, but also after the sample has been sufficiently mixed with the chemical constituents of the reagent layer (see col. 08:18-33). With this desire in mind, since it was known at the time of the invention that the profiles of the fluid flow fronts in microchannels can have different shapes, such as concave or convex, depending on the fluid, chemistry of the

capillary surface, contamination, and surface roughness (see Microsystem Design) one with ordinary skill in the art would adapt the fill detection region so as not to be influenced in its fill sufficiency determination by the shape of the fluid flow front. Neel, in fact, discloses three ways of adapting the embodiment of Figure 2 that would create a response as claimed, although not stated to do so: (a) placing the second fill detection electrode behind the first fill detection electrode, which would practically ensure that the measurement zone has been substantially occupied before response above a predetermined threshold is given (col. 08:18-33); (b) narrowing the capillary region over the fill electrodes (col. 08:18-33); or (c) changing the threshold (determined by calibration) for determining whether a response indicates that the measurement zone has been substantially occupied (col. 14:11-26).

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 5, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a fluid flow intake opening (68), a fluid flow terminus (70), a reagent (90) disposed on the test strip between the opening and the terminus (Figure 3), the reagent defining a measurement zone (Figures 2 and 3), and at least two dose sufficiency electrodes (60, 62) defining a gap therebetween (Figure 2) and located between the measurement zone and the terminus (Figure 2); applying the biological fluid to the opening (344- Figure 17), whereby the fluid flows from the opening toward the terminus (col. 14:43-51 and col. 14:63-65); applying a test signal to a first one of the electrodes (col. 14:66 – col. 15:03); determining the presence or absence of a response above a predetermined threshold at the second one of the electrodes, the response indicating that the fluid has occupied substantially all of the measurement zone (col. 15:03-11).

Neel does not mention whether the flow includes a flow front selected from one of a concave, a convex and a substantially flat flow front and thus whether the response indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to have the fill detection region adapted (if not already so adapted) so that the response of the second fill electrode indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat because Neel desires for the sample to reach the

fill electrodes not only until after the sample has traversed the reagent layer, but also after the sample has been sufficiently mixed with the chemical constituents of the reagent layer (see col. 08:18-33). With this desire in mind, since it was known at the time of the invention that the profiles of the fluid flow fronts in microchannels can have different shapes, such as concave or convex, depending on the fluid, chemistry of the capillary surface, contamination, and surface roughness (see Microsystem Design) one with ordinary skill in the art would adapt the fill detection region so as not to be influenced by the shape of the fluid flow front. Neel, in fact, discloses three ways of adapting the embodiment of Figure 2 that would create a response as claimed, although not stated to do so: (a) placing the second fill detection electrode behind the first fill detection electrode, which would practically ensure that the measurement zone has been substantially occupied before response above a predetermined threshold is given (col. 08:18-33); (b) narrowing the capillary region over the fill electrodes (col. 08:18-33); or (c) changing the threshold (determined by calibration) for determining whether a response indicates that the measurement zone has been substantially occupied (col. 14:11-26).

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill

chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 9, for the additional limitations of this claim see Figures 1-3 in Neel and note capillary fill chamber (88) and reagent (90).

5. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design") as applied to claims 1, 5, and 9 above, and further in view of Beaty et al. (WO 99/32881 A1) ("Beaty") and Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London **14** 327-336) ("Bedell").

Neel as modified by Microsystem Design uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as modified by Microsystem Design because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

For claims 3, 4, 7, and 8 note that Beaty states, "The real and imaginary components of the AC *impedance* of the biosensor ...through a suitable frequency range ... throughout some portion of which the parameter to be determined, be it sample identity, sample *volume*, ... *varies with sufficient magnitude and phase* and is optimally uncoupled from, that is independent from, the concentration of other components of the sample on the cell 31. [emphasis added]" See page 16:20-30. For claim 4 further note that admittance is the reciprocal of impedance. See the Bedell article, especially the second full paragraph on page 328 and the last full paragraph on page 332. Thus, barring a contrary showing, having the response comprise an admittance value is an obvious variant of a response that has an impedance value.

6. Claims 10, 11, 14-17, 20-22, 25-29, 32, 33, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of Beaty et al. (WO 99/32881 A1) ("Beaty").

Addressing claims 10 and 11, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a capillary fill chamber (88) extending a length along the test strip,

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

applying a biological fluid to the test strip (344 – Figure 17 and col. 04:25-34);

applying a dose sufficiency test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the dose sufficiency test signal at the other of the dose sufficiency electrodes (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 14, and 25, for the additional limitations of these claims note that Applicant himself discloses an edge effect occurs when an AC test signal is applied to dose sufficiency electrodes placed nearly side-by-side, except for a small gap. See the bottom paragraph on page 56 of the specification. That, is based on Applicant's disclosure, an edge effect as shown in Applicant's Figure 36 would be an expected *property* when an AC test signal, as taught by Beaty, is applied to the similarly situated dose sufficiency electrodes in Figures 2 and 3 of Neel.

Addressing claims 15 and 26, for the additional limitations of these claims see in Beaty page 16:20-24.

Addressing claims 16 and 17, Neel discloses a method of determining a fill sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), including: a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber and located between the measurement zone and the terminus (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus whereby the chamber is filled (344 – Figure 17 and col. 04:25-34);

applying a test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

detecting a response or an absence of the response to the test signal at the other of the dose sufficiency electrodes effective to indicate the fill sufficiency of the biological fluid (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

Addressing claims 20 and 22, Neel discloses a method of determining a dose sufficiency in a test strip for performing a measurement on a biological fluid (Figures 1-3), comprising:

providing a biological fluid test strip comprising:

a fluid flow intake opening (68);

a fluid flow terminus (70);

a reagent (90) disposed on the test strip between the opening and the terminus (Figure 3), the reagent defining a measurement zone (Figures 2 and 3);

and at least two dose sufficiency electrodes (60, 62) defining a gap therebetween and located between the measurement zone and the terminus (Figure 2);

applying the biological fluid to the test strip (col. 14:66 – col. 15:03);

applying a dose sufficiency test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and measuring a response to the dose sufficiency test signal at the other of the dose sufficiency electrodes (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because

as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 21 and 28, for the additional limitations of this claim see Figures 1-3 and note capillary fill chamber (88).

Addressing claims 27 and 29, Neel discloses a method of determining a fill sufficiency in a test strip for performing a measurement on a biological fluid (Figures 1-3), comprising:

providing a biological fluid test strip comprising:

a fluid flow intake opening (68);

a fluid flow terminus (70);

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

and at least two dose sufficiency electrodes (60, 62) positioned intermediate the measurement zone and the terminus (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus (344 – Figure 17 and col. 04:25-34);

applying a test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

detecting a response or an absence of the response to the test signal at the other of the dose sufficiency electrodes effective to indicate the volume sufficiency of the biological fluid (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 32 and 33, Neel discloses a method of determining dosage fill level in a test strip for performing a measurement on a biological fluid comprising:

providing a biological fluid test strip (Figures 1-3), including:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2) the dose sufficiency electrodes (60, 62) positioned to define a gap between one another (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to begin to fill the chamber (344 – Figure 17 and col. 04:25-34);

applying a test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the signal at the other of the dose sufficiency electrodes (col. 15:03-11);

determining whether there is a sufficient dosage level (col. 15:03-11 and col. 14:11-26).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined

with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

Addressing claim 36, for the additional limitation of this claim note that Applicant discloses that when an AC test signal is applied to dose sufficiency electrodes placed nearly side-by-side, except for a small gap, "... there is substantially no electrical communication between the electrodes until the sample covers at least a portion of the edges along the electrode gap." See the bottom of page 56 of the specification to the last paragraph on page 57. That is, that the response varies in correlation with the degree to which the biological fluid bridges the gap would be an expected *property* when an AC test signal, as taught by Beaty, is applied to the similarly situated dose sufficiency electrodes in Figures 2 and 3 of Neel.

Addressing claims 37 and 38, Neel discloses a method of determining a fill level in a test strip for performing a measurement on a biological fluid comprising:

providing a test strip (Figures 1-3) including:

a capillary fill chamber (88) extending a length along the test strip from an opening (68) to a terminus (70),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2) the dose sufficiency electrodes (60, 62) positioned to define a gap between one another (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus whereby the chamber is filled (344 – Figure 17 and col. 04:25-34);

applying a test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the signal at the other of the dose sufficiency electrodes (col. 15:03-11);

determining whether there is a sufficient dosage level (col. 15:03-11 and col. 14:11-26).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

7. Claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of Beaty et al. (WO 99/32881 A1) ("Beaty") as applied to claims 10, 11, 14-17, 20-22, 25-29, 32, 33, 36-38 above, and further in view of Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London **14** 327-336) ("Bedell").

Addressing claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 for the additional limitations of these claims note that Beaty states, "The real and imaginary components of the AC *impedance* of the biosensor ...through a suitable frequency range ... throughout some portion of which the parameter to be determined, be it sample identity, sample *volume*, ... *varies with sufficient magnitude and phase* and is optimally uncoupled from, that is independent from, the concentration of other components of the sample on the cell 31. [emphasis added]" See page 16:20-30. For claim 4 further note that admittance is the reciprocal of impedance. See the Bedell article, especially the second full paragraph on page 328 and the last full paragraph on page 332. Thus, barring a contrary showing, having the response comprise an admittance value is an obvious variant of a response that has an impedance value.

8. Claims 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel").

Addressing claim 60, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the capillary chamber and second edges substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first edges be of a greater length than the second edges and, in fact, Figure 2 shows that second edges being of a greater length than the first edges. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first edges greater than the length of the second edges. Barring a contrary showing, such as unexpected results, having the length of the first edges be greater than the length of the second edges is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

Addressing claim 61, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber the electrodes positioned intermediate the measurement zone and the terminus (Figures 2 and 3);

wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the capillary chamber and a second axis substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first axis be of a greater length than the second axis and, in fact, Figure 2 shows that the second axis has a greater length than the first axis. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first axis greater than the length of the second axis. Barring a contrary showing, such as unexpected results, having the length of the first axis be greater than the length of the

second axis is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 62, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a fluid flow path (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the capillary chamber and second edges substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first edges be of a greater length than the second edges and, in fact, Figure 2 shows that second edges being of a greater length than the first edges. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first edges greater than the length of the second edges. Barring a contrary showing, such as unexpected results, having the length of the first edges be greater than the length of the second edges is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

Addressing claims 63 and 65, for the additional limitations of these claims see col. 06:60 – col. 07:12 in Neel.

Addressing claim 64, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a fluid flow path (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber the electrodes positioned intermediate the measurement zone and the terminus (Figures 2 and 3);

wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the capillary chamber and a second axis substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first axis be of a greater length than the second axis and, in fact, Figure 2 shows that the second axis has a greater length than the first axis. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first axis greater than the length of the second axis. Barring a contrary showing, such as unexpected results, having the length of the first axis be greater than the length of the second axis is just a consequence of optimizing the widths of different portions of the

capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 51, 52, 57, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention: claims 51, 52, 57, and 58 refer to "the response"; however, claims 50 and 54 have both a "first response" and a "second response".

Allowable Subject Matter

11. Claims 41-50, 53-56, and 59 are allowed.

12. Claims 2-4, 6-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 51, 52, 57, and 58 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

a) Claims 2 and 6: each combination of limitations requires the test signal to be an AC signal and also requires either "at least two dose sufficiency electrodes defining a gap therebetween (Figure 2) and in operative communication with the capillary ... the electrodes located between the measurement zone and the terminus" or "at least two measurement electrodes in operative communication with the chamber, and at least two dose sufficiency electrodes in operative communication with the chamber."

Neel uses a DC voltage for the test signal (implied by col. 14:11-26). In an analogous arrangement to the embodiment shown in Figure 2 of Neel in which the detection electrodes are nearly side-by-side, except for a small gap, and adjacent the terminus of the sample fill chamber Applicant has found that when the fill detection electrodes are used with a DC or low frequency test signal they work best when the fluid front is convex, but may not, however, produce ideal results for a concave fluid front. See the last paragraph on page 54 of the specification, bridging to page 55. When the test signal is a relatively high frequency AC signal the fill detection electrodes exhibit edge effects that will avoid the problem of a response indicating a conclusion of dose sufficiency even though sample has not contacted electrode edges along the gap between them. See the bottom paragraph on page 56, bridging to the top of page 58 of the specification.

Beaty (US 6,645,368 B1) discloses using an AC test signal to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col.

06:20-42. However, Beaty does not have the two does sufficiency electrodes located between the measurement zone and the terminus or two measurement electrodes in addition to the two dose sufficiency electrodes as the two dose sufficiency electrodes in Beatty (and also in the patents and the application listed in col. 06:20-23) are also the measurement electrodes.

b) Claims 3 and 7: each combination of limitations requires the response to comprise magnitude and phase angle information. The response in Neel is a current magnitude without phase signal information since the test signal is a DC signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses using an AC test signal to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42. However, Beaty does not have the two does sufficiency electrodes located between the measurement zone and the terminus or two measurement electrodes in addition to the two dose sufficiency electrodes as the two dose sufficiency electrodes in Beatty (and also in the patents and the application listed in col. 06:20-23) are also the measurement electrodes.

c) Claims 4 and 8: each combination of limitations requires the response to comprise an admittance value. The response in Neel is a current magnitude (col. 14:11-26).

d) Claim 41: the combination of limitations requires "at least two pairs of dose sufficiency electrodes in operative communication with the chamber, each of the pairs of dose sufficiency electrodes positioned to define a respective gap between one another." By providing multiple pairs of dose sufficiency electrodes each at a different distance from the measurement zone" the capability to assess the extent of capillary space 3306 filling may be provided by examining which of the multiple pairs of dose sufficiency electrodes has been bridged by the sample." See page 55 of the specification.

Neel only provides a pair of dose sufficiency electrodes, which is located between the measurement zone and the terminus of the capillary fill chamber.

In Beaty there is only one pair of electrodes, which runs the length of the capillary fill chamber, as the two dose sufficiency electrodes in Beaty (and also in the patents and the application listed in col. 06:20-23 of Beaty).

e) Claims 42- 44 depends from allowable claim 41.

f) Claim 45: the combination of limitations requires "at least two pairs of dose sufficiency electrodes positioned between the reagent and the terminus, each of the pairs of dose sufficiency electrodes defining a respective gap between one another."

By providing multiple pairs of dose sufficiency electrodes each at a different distance from the measurement zone" the capability to assess the extent of capillary space 3306 filling may be provided by examining which of the multiple pairs of dose sufficiency electrodes has been bridged by the sample." See page 55 of the specification.

Neel only provides a pair of dose sufficiency electrodes, which is located between the measurement zone and the terminus of the capillary fill chamber.

In Beaty there is only one pair of electrodes, which runs the length of the capillary fill chamber, as the two dose sufficiency electrodes in Beaty (and also in the patents and the application listed in col. 06:20-23 of Beaty).

g) Claims 46- 48 depends from allowable claim 45.

h) Claims 49 and 54: each combination of limitations requires the step of "determining a rate at which the biological fluid fills the chamber based at least in part upon the first response and the second response.

Neel only discloses providing a fill timer that sets a time limit for the sample, such as blood, to traverse the reagent layer and reach the dose sufficiency electrodes. See col. 14:63 – col. 15:11. Thus, Neel teaches away from determining the rate at which the biological fluid fills the chamber since Neel presets the time by which a response at a dose sufficiency electrode must exceed a threshold current value.

Beaty only discloses that when an impedance determination is made during the measurement the measurement time can be reduced four-fold compared to prior art techniques. See page 19, line 17 – page 20, line 4.

i) Claims 50- 53 depends from allowable claim 49.

j) Claims 55- 59 depends from allowable claim 54.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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